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DEPARTMENT OF HEALTH AND HUMAN SERVICE Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

Telephone: 504-589-6341
FAX: 504-589-6360

June 30, 1999

WARNING LETTER NO. 99-NOL-36

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Allen J. Marie, Owner/President
Madison Seafood Incorporated
2166 Highway 55
Montegut, Louisiana 70377-3112

Dear Mr. Marie:

On March 4, 10-11, 1999, an investigator of the U. S. Food and Drug Administration (FDA) conducted an inspection of your shrimp processing facility, located at 2166 Louisiana Highway 55, Montegut, Louisiana. The investigator documented that your firm was not in compliance with FDA's seafood processing regulations and the Good Manufacturing Practices requirements for foods. This causes your finished products, fresh raw shrimp and dried shrimp, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, in that you failed to operate in accordance with the requirements of Title 21, *Code of Federal Regulations* (CFR), Part 123, covering the Processing and Importing of Fish and Fishery Products and the Current Good Manufacturing Practice (CGMP) regulations for foods (21 CFR 110).

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the March 1999 inspection, the FDA investigator observed shortcomings in your system that were similar to those pointed out in the March 10 and 12, 1998, inspection

and stated in the untitled letter sent to your firm on July 7, 1998. The FDA investigator also provided your firm with a copy of the Domestic Seafood HACCP Report (Form FDA-3501) and the Form FDA-483, which presents his evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. The Form FDA-483 is enclosed for your review. The observations of concern to us are as follows:

- Failure to record the actual values and observations obtained during monitoring, as required by 21 CFR, Part 123.6(c)(7), in that the monitoring logs do not include the actual times for the start and end of each cook cycle;

- Failure to verify that the HACCP plan for dried shrimp is adequate to control pathogen survival through the cook step, as required by 21 CFR, Part 123.8(a);

- Failure to monitor the critical limit of a water activity of 0.85 or less within [redacted] in your dried shrimp product as stated in your HACCP plan, as required by 21 CFR, Part 123.6(b); and,

- Failure to adequately monitor sanitation in that the firm is not monitoring for the prevention of cross contamination, maintenance of hand washing and hand sanitizing, protection from adulterants, control of employees with adverse health conditions and the exclusion of pests on February 1-5, 1999, February 15-19, 1999 and March 1-5, 1999, as required by 21 CFR, Part 123.11(b).

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the FDA Form 483. However, as the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Nicole F. Hardin, Compliance Officer, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Hardin at (504) 589-7166.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483